

January 16, 1990

Mr. Steve A. Spinosa
Medical Physics Operations
Mallinckrodt Medical, Inc.
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P. O. Box 5840
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Thank you for your letters of October 4 and November 29, 1989, with regard to the regulation of radiopharmaceuticals under the Medical Waste Tracking Act of 1988 (MWTa). As you are well aware, these types of wastes are subject to regulation by both the Nuclear Regulatory Agency and the Environmental Protection Agency. The regulations for medical waste management found at 40 CFR Part 259 apply only to medical waste generated in those states in the demonstration program (New York, New Jersey, Rhode Island, Connecticut and Puerto Rico) and are effective through June 22, 1991.

The purpose of the demonstration program is to provide control over the shipping of medical waste and gather much needed information on medical waste management activities as required by congress. The Part 259 regulations therefore meet the intent of the MWTa statute. While the implementation of the Part 259 regulations may have resulted in changes in the methods medical facilities have traditionally used for "medical waste" management, the Agency does not feel these regulations have disrupted the provision of health care. In your letters you have discuss several concerns your company has in regard to the implementation of the regulations published as a result of the MWTa, and consequently your company has requested an exemption for radiopharmaceuticles from Part 259 regulations covering medical waste management.

Your request for an exemption from regulation and comments on the Part 259 regulations will be placed in the RCRA docket and will be considered to the extent appropriate, when final rule changes are promulgated or recommendations to Congress are made. However, in clarification of several points made in your letters, Mallinckrodt should be aware of the following information concerning treatment of regulated medical waste and use of the medical waste tracking form.

Your letter indicated that residual radiopharmaceutical materials from medical facilities are recovered by Mallinckrodt personnel and returned to the radiopharmacy, at Mallinckrodt, for decay and eventual disposal. This service provided by Mallinckrodt to a certain extent provides a form of treatment for these wastes as defined in Section 259.10 (a), which states that treatment is "any method technique, or process designed to change the biological character or composition of any regulated medical waste so as to reduce or eliminate its potential for causing disease." Even though allowing a material to decay does not constitute treatment of the infectiousness of the waste, this procedure does

change the radioactive composition of the waste to reduce its potential for causing disease. Mallinckrodt, therefore, acts as an intermediate handler of these radiopharmaceutical wastes and must meet all the requirements for Part 259 Subpart I.

Tracking forms, as noted in Section 259.52, are required for off-site transport of regulated medical waste. Mallinckrodt may wish to consolidate their radioactive waste recovery activities at facilities which utilize these services in order to avoid the necessity for additional tracking forms for multiple shipments.

If you need further information or have additional questions please contact Michaelle Wilson at 202-382-4669.

Sincerely,

Devereaux Barrens

cc: Austin Farewell
Susan Bromm

FaxBack # 11485